

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. – 6. (Cancelled)

7. (Currently Amended) A process to prepare a sustained release solid protein drug characterized by ~~comprising~~ consisting essentially of:

(a) preparing a mixture of a protein ~~proteins~~ and a sulfated polysaccharide ~~sulfated polysaccharides~~ at room temperature to form a complex of the protein and the sulfated polysaccharide,

(b) suspending the mixture obtained in (a) in a ~~non-aqueous~~ solution containing hydrophobic materials selected from fatty ~~acids~~ acid, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof, and

(c) removing a solvent from the suspension to obtain a solid protein drug;¹

wherein the pH of the mixture of the protein ~~proteins~~ and the sulfated polysaccharide ~~sulfated polysaccharides~~ is lower than the isoelectric point of the protein.

8. (Original) The process of claim 7 wherein said sulfated polysaccharide is selected from dextran sulfate, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, and keratan sulfate.

9. (Cancelled)

10. (Original) The process of claim 7 wherein said sulfated polysaccharide is present in an amount of from 0.01 to 95% weight of the formulation.

11. (Original) The process of claim 7 wherein the mixture of protein and sulfated polysaccharide is a solid microparticulate form.

12. (Original) The process of claim 11 wherein said solid microparticulate is prepared by drying the liquid mixture of protein and sulfated polysaccharide.

13. (Original) The process of claim 12 wherein said solid microparticulate is obtained by spray drying, freeze drying, spray freeze drying, and drying using supercritical fluid.

14. (Original) The process of claim 7 wherein the mixture of protein and sulfated polysaccharide is a liquid state.

15. (Cancelled)

16. (Cancelled)

17. (Previously Presented) The process of claim 25 wherein said protein stabilizer is selected from sucrose, trehalose, maltose, mannitol, lactose, mannose, polyol, dextran,

polyethyleneglycol, cyclodextrin, polyvinylalcohol, hydroxypropylmethylcellulose, hydroxyethylcellulose, polyethyleneimine, polyvinylpyrrolidone, gelatin, collagen, albumin, surfactants, amino acids, inorganic salts, and mixtures thereof.

18. (Cancelled)

19. (Cancelled)

20. (New) A sustained release solid formulation characterized by consisting essentially of protein drug, sulfated polysaccharide, and hydrophobic material selected from fatty acids, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof, wherein the mixture of protein and sulfated polysaccharide is encapsulated within a matrix of the hydrophobic material, and the sustained release solid formulation is prepared by the process of claim 7.

21. (New) The formulation of claim 20, wherein said sulfated polysaccharide is selected from dextran sulfate, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, and keratan sulfate.

22. (New) The formulation of claim 20, wherein sad sulfated polysaccharide is present in an amount of from 0.01 to 95% weight of the formulation.

23. (New) A sustained release solid formation consisting essentially of the formulation of claim 20 and protein stabilizers.

24. (New) The formation of claim 23 wherein said protein stabilizer is selected from sucrose, trehalose, maltose, mannitol, lactose, mannose, polyol, dextran, polyethyleneglycol, cyclodextrin, polyvinylalcohol, hydroxypropylmethylcellulose, hydroxyethylcellulose, polyethyleneimine, polyvinylpyrrolidone, gelatin, collagen, albumin, surfactants, amino acids, inorganic salts, and mixtures thereof.

25. (New) A process to prepare a sustained release solid protein drug consisting essentially of:

(a) preparing a mixture of a protein and a sulfated polysaccharide at room temperature to form a complex of the protein and the sulfated polysaccharide, and further adding a protein stabilizer to the mixture;

(b) suspending the mixture obtained in (a) in a solution containing hydrophobic materials selected from fatty acids, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof; and

(c) removing a solvent from the suspension to obtain a solid protein drug;

wherein the pH of the mixture of the protein and the sulfated polysaccharide is lower than the isoelectric point of the protein.